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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,987	10/23/2003	Steven M. Griffiths	11201-728-999	4737

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT PAPER NUMBER

3767

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,987

Applicant(s)

GRIFFITHS ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 29-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment filed 10 October 2006.

Election/Restrictions

1. This application contains claims 1-20 drawn to an invention nonelected with out traverse in Paper No. 11/07/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

The amended claims contain subject matter which was not found in the parent applications which the present application claims benefit from as a continuation-in-part. Patents 6,641,561 and 6,770,052 do not disclose the aseptic and low-particulate environments, therefore the claims are given the filing date of the present application, 23 October 2003.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szapiro et al (US 6,602,223) in view of van der Wal (US 5,569,192).

Regarding claim 29, Szapiro et al teaches a method of providing a syringe comprising inserting a seal (4 and 5) into a chamber (1) to divide the chamber, the seal being

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placed at a location of the user's choice, and the seal having a flow path (14 and 15) formable therethrough, filling the rear compartment (10) with a first medicament, sealing the rear end (via 7), and filling the front compartment (2) with a second medicament and sealing the front end (via 6). Szapiro does not expressly teach that (10) is a wet medicament and (2) is filled with a dry medicament, but it is well known in the art to provide a two-chamber syringe in this configuration, as taught, for example, by van der Wal. Since the liquid is in the rear compartment, the action of the plug (4 and 5) would not be destroyed if the front compartment were filled with a dry medicament. It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a dry medicament in the front chamber, as taught by van der Wal, in order to provide a prefilled syringe containing a component which needs to be reconstituted prior to delivery, such as a freeze-dried vaccine.

Regarding claim 30, Szapiro places a tapered insert (6) into the front end of the chamber.

Regarding claim 31, a needle assembly (11) is attached to the front end.

Regarding claim 32, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place the wet medicament in the syringe first, as there are a finite number of ways (two) to load the syringe without mixing the two medicaments.

Regarding claim 33, the rear end is sealed by a plunger (7 and 8)

Regarding claims 34-36, the dry medicament portion may be a powder or a tablet as disclosed by van der Wal (see Col 4, last full paragraph)

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4. Claims 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szapiro in view of Odell et al (US 6,263,641).

Szapiro teaches the structural limitations of the syringe being formed as shown above, but does not teach the steps of placing the syringe in an aseptic or low-particulate environment. Odell et al teaches a method of making and assembling medical containers involving using sterile environments (for Figures 1-4) and placing the syringes in a low-particulate environment (when filling the dry component, Col 13 lines 33-50), then packaging the syringes in sterile packaging (an aseptic environment).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of assembly of Odell with the device of Szapiro in order to provide a pre-filled syringe which is safe to use and contains uncontaminated medicament.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elizabeth R. MacNeill
12/5/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons